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# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE SCHERING-PLOUGH CORPORATION/ENHANCE SECURITIES LITIGATION 08-CV-397 (DMC) (JAD)

Oral Argument Requested

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
MOTION FOR PARTIAL SUMMARY JUDGMENT

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#### **Preliminary Statement**

This case involves Plaintiffs' claim that Defendants delayed in disclosing that the ENHANCE trial had failed. Plaintiffs concede that the trial's failure became public on January 14, 2008, and they have sought damages for the decline in Schering's stock prices on January 14 and 15. Ordinarily, that would be the extent of the lawsuit. But in this case, Plaintiffs seek additional damages for stock drops on December 12, 2007, January 17, 2008, January 25, 2008, January 29, 2008, and March 31, 2008. Plaintiffs do not claim that the ENHANCE trial's failure became public on those days; that happened on January 14, 2008. Instead, they argue that disclosures on those days, and the consequent drops in stock price, were "foreseeable" and constituted the "materialization of a concealed risk."

Plaintiffs' claim for damages on any day other than January 14-15 should be rejected. The Third Circuit has never applied the "materialization of concealed risk" theory for establishing loss causation. It requires, instead, that the loss arise from disclosure of the alleged fraud. In this case, that occurred on January 14, when Defendants disclosed that the ENHANCE trial had failed. Moreover, even under Plaintiffs' theory, their claim must fail. That is because, after January 14, the risks associated with the failure of the ENHANCE trial were unconcealed. For these reasons, and the others set out below, partial summary judgment should be granted dismissing Plaintiffs' claim for damages based upon stock drops on December 12, 2007, January 17, 2008, January 25, 2008, January 29, 2008, and March 31, 2008.

#### Argument

I.

## LOSS CAUSATION MUST BE MEASURED FROM JANUARY 14, 2008 BECAUSE THAT IS WHEN THE ALLEGED FRAUD WAS DISCLOSED

Plaintiffs allege that Defendants "knew or recklessly disregarded that the ENHANCE trial would fail to show an IMT benefit for Vytorin versus simvastatin." (Affidavit of Andrew G. Gordon, sworn to March 1, 2012 ("Gordon Aff."), Ex. 24 at 75; Pl. SOF ¶ 1.) And they cannot dispute that Defendants disclosed precisely this information on January 14, 2008, when Defendants announced that the ENHANCE trial had failed. (Gordon Aff., Ex. 2.)

Indeed, Plaintiffs provided the Court with numerous newspaper articles from that day stating that the study "failed to find any positive benefit" from Vytorin, the "drug doesn't work," the ENHANCE results were "as bad a result for the drug as anybody could have feared," and there was "no support for prescribing this drug at this point." (Gordon Aff., Ex. 1 ¶ 174; Ex. 34; Exs. 27-29; Ex. 23 at 15, 22-23.) Plaintiffs even filed a complaint on January 18, 2008, in which they stated that "investors were shocked and alarmed" to learn on January 14, 2008 that the Schering-Plough "defendants had purposefully delayed the publication of a study that they possessed throughout the Class Period." (Gordon Aff., Ex. 30, ¶ 60.) There is, then, no dispute that Defendants' disclosure on January 14 revealed the fraud Plaintiffs allege in this case. Based on this disclosure, Plaintiffs seek damages for declines in the price of Schering-Plough securities on January 14 and 15, 2008.

But Plaintiffs are not content to stop there. They also argue that they are entitled to recover for losses incurred on December 12, 2007, January 17, 2008, January 25, 2008, January 29, 2008, and March 31, 2008. Plaintiffs cannot claim that the alleged fraud was disclosed on those days. Instead, they argue that these dates reflect the disclosure of "materialized risks" which were "foreseeable" consequences of the alleged fraud. (Pl. Br. 9.)

Plaintiffs' materialization of the risk argument should be rejected because, as Judge Wolfson recently noted, the "Third Circuit has not endorsed this type of pleading as a way to establish loss causation." *Nat'l Junior Baseball League* v. *Pharmanet Dev. Grp., Inc.*, 720 F. Supp. 2d 517, 563 n.35 (D.N.J. 2010). The Third Circuit has explained that it is not enough to ask "whether or not the loss was simply foreseeable." *Newton* v. *Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 181 n.24 (3d Cir. 2001). Rather, plaintiffs must prove that the "very facts" about which the defendant allegedly lied caused the injuries claimed. *See McCabe* v. *Ernst & Young, LLP*, 494 F.3d 418, 425-30 (3d Cir. 2007) (affirming summary judgment for defendant on loss causation grounds, and noting that loss causation limits liability so that an issuer does not become an "insurer"); *Berckeley Inv. Grp., Ltd.* v. *Colkitt*, 455 F.3d 195, 222-23 (3d Cir. 2006) (affirming summary judgment for defendant on loss causation grounds, and describing loss causation as an "exacting standard").

Plaintiffs state that "Dura and its progeny make clear that while 'the very facts about which the defendant lied' must 'cause[] [plaintiff's] injuries,' Berckeley, 455 F.3d at 222, the law does not prescribe the form the disclosure of

those facts must take, or the manner in which they must cause the loss." (Pl. Br. 12.) Thus, they note that loss causation can be shown "indirectly" through a series of third-party disclosures that "partially" reveal the alleged fraud. (Pl. Br. 9-10.) But none of that is relevant where, as here, there was – in fact – a single disclosure by the issuer of the very facts comprising the alleged fraud. After that date, other disclosures that do not reveal the alleged fraud cannot be corrective. *See*, *e.g.*, *McKowan Lowe & Co.*, *Ltd.* v. *Jasmine*, *Ltd.*, 231 F. App'x 216, 218 (3d Cir. 2007) (affirming dismissal on loss causation grounds, since loss causation requires stock drop to be caused by revelation of the "truth that was allegedly concealed").

Plaintiffs also complain that Defendants' position on the "very facts" test would require a "mirror image" corrective disclosure. (Pl. Br. 10-12.) But that is not Defendants' position. Instead, it is that Plaintiffs must show that their loss was caused by disclosure of the alleged fraud. It is "the exposure of the falsity of the fraudulent representation [to the market] that is the critical component" of loss causation. *In re DVI, Inc. Sec. Litig.*, 03-cv-5336, 2010 WL 3522090, at \*11 (E.D. Pa. Sept. 3, 2010) (citation omitted).

There is good reason for this rule. As the Supreme Court explained in *Dura*, private securities actions are "available, not to provide investors with broad insurance against market losses, but to protect them against those economic losses

See also Pharmanet, 720 F. Supp. 2d at 562-63 (a corrective disclosure must reveal to the market "the so-called 'truths'" that defendants allegedly withheld); In re Omnicom Grp., Inc. Sec. Litig., 541 F. Supp. 2d 546, 552 (S.D.N.Y. 2008), aff'd, 597 F.3d 501, 511 (2d Cir. 2010) ("where a disclosure does not reveal the falsity of the alleged misstatements, it does not qualify as 'corrective'").

that misrepresentations actually cause." *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 343, 345 (2005). They do not provide recovery for losses that might arguably "touch upon" an alleged fraud; they impose responsibility only for losses that were actually caused by a defendant's fraudulent conduct. *Id.* at 343. The Third Circuit echoed this same rationale in *McCabe*, 494 F.3d at 425 n.3, where it cautioned that loss causation limits liability so that a defendant does not become an "insurer against all the risks associated with [the] investment."

Plaintiffs suggest that *McCabe* adopted their theory because it cited a law review article addressing the "materialization of concealed risk" approach within a broader discussion of loss causation principles. (Pl. Br. 9.) While the court stated that the preceding discussion was "consistent with our loss causation jurisprudence," *McCabe*, 494 F.3d at 429, the Third Circuit did not apply the "materialization of concealed risk" theory in *McCabe* or elsewhere. More recently, the Third Circuit's opinion in *DVI* – unlike the earlier district court opinion in *DVI* on which Plaintiffs rely – did not mention the "materialization of a concealed risk" theory, but instead used the traditional "corrective disclosure" analysis for determining whether a disclosure exposes the falsity of an alleged misrepresentation. *See In re DVI, Inc. Sec. Litig.*, 639 F.3d 623, 634-39 & n.17 (3d Cir. 2011).

Moreover, Plaintiffs' argument would fail even if this Court were to be guided by the "materialization of concealed risk" theory. This approach permits a plaintiff to plead loss causation where the loss that materialized was "within the zone of risk *concealed* by the [alleged] misrepresentations." *In re Omnicom Grp.*,

Inc. Sec. Litig., 597 F.3d 501, 513 (2d Cir. 2010) (emphasis in original; citation omitted). Foreseeability of the loss is a necessary condition, but it "is not enough to establish loss causation; Plaintiffs must also allege that the loss was caused by the materialization of the concealed risk." Waters v. Gen. Elec. Co., 08-cv-8484, 2010 WL 3910303, at \*8 (S.D.N.Y. Sept. 29, 2010), aff'd sub nom., G.E. Investors v. Gen. Elec. Co., 2011 WL 5607137 (2d Cir. Nov. 18, 2011) (summary order) (after relevant risks were unconcealed, investors could not recover for "foreseeable consequences" that materialized the very next day).<sup>2</sup>

In short, what is critical to this approach is that the loss must materialize at a time when there has been no prior disclosure of the alleged fraud, so that the relevant risks remain concealed from the public. By contrast here, when the failure of the ENHANCE trial was disclosed, any risks associated with that failure were *unconcealed*. After January 14, 2008, the risks allegedly concealed by Defendants – the failure of the ENHANCE trial – were revealed.

See also In re Flag Telecom Holdings, Ltd. Sec. Litig., 574 F.3d 29, 40 (2d Cir. 2009) (plaintiffs must "prove that the loss they suffered was both foreseeable and caused by the 'materialization of the concealed risk"); Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 173 (2d Cir. 2005) (requiring "both that the loss be foreseeable and that the loss be caused by the materialization of the concealed risk") (emphasis in original).

II.

# DISCLOSURES ON DATES OTHER THAN JANUARY 14, 2008 DID NOT REVEAL THE VERY FACTS ALLEGEDLY WITHHELD

### A. The Events Of December 11, 2007 Do Not Show Loss Causation

Plaintiffs allege that a decline in Schering's stock price on December 12, 2007, is attributable to an announcement on the 11th of a Congressional investigation into the delay in announcing the results of the ENHANCE trial. (Gordon Aff., Ex. 26 ¶¶ 161-62.) Plaintiffs, however, do not contend that the announcement identified any new facts about the ENHANCE trial or said anything about whether Vytorin would outperform Zocor in the trial, so as to reveal a thenundisclosed fact with regard to the alleged misrepresentations. In fact, just last year, in In re Moody's Corp. Sec. Litig., 274 F.R.D. 480, 487-88 (S.D.N.Y. 2011), the court rejected precisely this argument, finding that an announcement of a Congressional investigation did not constitute a "corrective disclosure" for purposes of loss causation. Moreover, the allegations of delay that Congress sought to investigate were not concealed as of December 11, 2007. Plaintiffs concede that those same allegations had been publicly reported between March and November 2007 over the internet, in the New York Times, and in other publications. (Gordon Aff., Ex. 1 ¶¶ 115, 120-21, 123-24, 131-34, 159-62; Ex. 14; Ex. 23 at 24 & n.59.) For both of these reasons, this claim must fail.

# B. The Events Of January 17, 2008 Do Not Show Loss Causation

Plaintiffs point to two disclosures on January 17. First, they note that Congress announced that it had expanded its investigation into Vytorin by raising

questions about Schering's advertising campaign for the drug. That announcement cannot be a "corrective disclosure," however, because it did not disclose a new fact about the fraud Plaintiffs allege – *i.e.*, Defendants' alleged delay of the ENHANCE trial. *See In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511-12 (2d Cir. 2010) (corrective disclosure requires a new "hard fact"); *In re Tellium, Inc. Sec. Litig.*, 02-cv-5878, 2005 WL 2090254, at \*4 (D.N.J. Aug. 26, 2005) ("*Dura* itself makes clear that loss causation is not pled upon allegations of drops in stock price following an announcement of bad news that does not disclose the fraud.").<sup>3</sup>
Moreover, the fact that the investigation was continuing was not new, as the same Congressmen had already announced on January 14: "it is clear that our investigation is far from over." (Gordon Aff., Ex. 34.)

Second, Plaintiffs argue that the market learned that sales of Vytorin and Zetia within the United States fell when UBS issued an analyst report on January 17. (Pl. Br. 30 & n.26.) This, too, is not a corrective disclosure because it also did not reveal the allegedly withheld ENHANCE results.

In addition, Plaintiffs concede that the data was disclosed "after the close of the market on January 17, 2008." (*Id.*) And Plaintiffs' economic expert

In their moving brief, Defendants cited cases holding that the opening of a governmental investigation is not a corrective disclosure where, as here, the investigation did not reveal any new information about the alleged fraud. (Def. Br. 19-20.) Plaintiffs responded with cases where, unlike here, the announcement actually revealed the alleged fraud. (Pl. Br. 37-38.) Plaintiffs' sole citation from this District, *In re Bradley Pharm., Inc. Sec. Litig.*, 421 F. Supp. 2d 822 (D.N.J. 2006), involved an SEC investigation that provided the first indication to the public of the accounting problems in question.

did not opine that the prescription data had any causal effect on Schering's stock price on January 17. Instead, he attributed the entire price decline on that day to the expanded Congressional investigation. (Gordon Aff., Ex. 26 ¶¶ 173-74.)<sup>4</sup> Thus, there is no evidence that the prescription data referenced in the UBS report, in fact, caused Schering's stock price to decline on January 17, 2008.

Finally, Plaintiffs cannot claim that the disclosures on January 17, 2008 were the "materialization of a concealed risk." The risks associated with the failure of the ENHANCE trial were *unconcealed* on January 14, 2008.

## C. The Events Of January 25, 2008 Do Not Show Loss Causation

Plaintiffs next argue that stock price declines on January 25, 2008, following the announcement of an FDA review of the ENHANCE results, show loss causation because it was foreseeable that delayed disclosure "could have negative legal and regulatory ramifications for Schering." (Gordon Aff., Ex. 26 ¶ 175; Ex. 33 at 206-07.) But the FDA announcement did not "correct any of the facts that the defendants had [allegedly] either withheld or misrepresented." (Gordon Aff., Ex. 33 at 206-08.) Accordingly, it cannot be a corrective disclosure of any "then-undisclosed fact with regard to the specific misrepresentations alleged in the complaint." *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511-12 (2d

<sup>4</sup> Plaintiffs speculate that the prescription data was "available for analysis" during the trading day on January 17 because on January 18, UBS received new data by 1:36pm. (Pl. Br. 30 & n.26.) Even Plaintiffs' own expert did not adopt this argument, and it is wholly insufficient to create a genuine dispute of material fact as to loss causation on January 17, 2008. See In re Ikon Office Solutions, Inc. Sec. Litig., 277 F.3d 658, 668 n.9 (3d Cir. 2002) (warning against reliance on mere allegations at summary judgment).

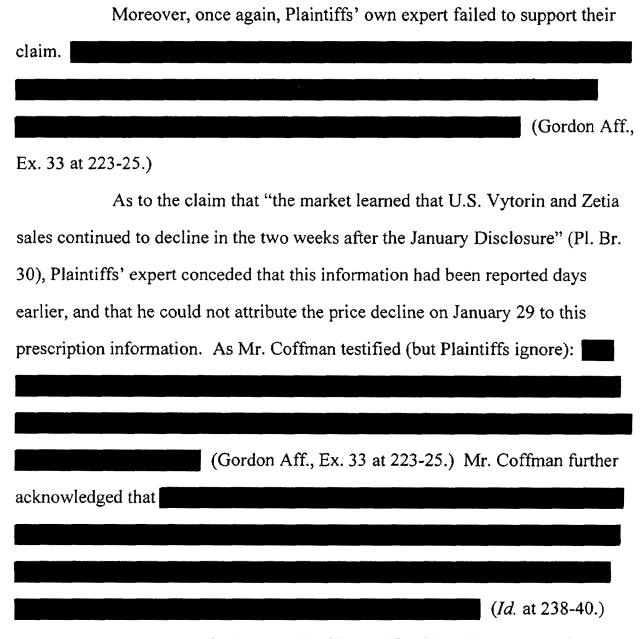
Cir. 2010). Insofar as Plaintiffs claim that the FDA review reflected foreseeable regulatory interest in the ENHANCE trial, that risk was unconcealed to the market as a whole by January 14, 2008. (Gordon Aff., Ex. 34.)

#### D. The Events Of January 29, 2008 Do Not Show Loss Causation

Plaintiffs contend that Schering's stock price declined on January 29, 2008, following a report that "Merrill Lynch was cutting its estimates for Schering due to lower predicted prescriptions and sales." (Pl. Br. 30.) Plaintiffs also assert that, on January 29, "the market learned that U.S. Vytorin and Zetia sales continued to decline in the two weeks after the January Disclosure." (*Id.*)

This argument is deficient for the same reasons as the other disclosures: "noticeably absent is any assertion that any wrongdoing was disclosed to the market." *Nat'l Junior Baseball League* v. *Pharmanet Dev. Group, Inc.*, 720 F. Supp. 2d 517, 561 (D.N.J. 2010). As numerous courts have held, analyst reports are not corrective disclosures where they do not "reveal to the market the alleged fraudulent nature of [defendant's] practices." *Katyle* v. *Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 475-76 (4th Cir. 2011).

See also Lentell v. Merrill Lynch & Co. Inc., 396 F.3d 161, 175 n.4 (2d Cir. 2005) (Merrill Lynch analyst downgrades not "corrective disclosures" because they did "not reveal to the market the falsity of the prior recommendations"); In re DVI, Inc. Sec. Litig., 03-cv-5336, 2010 WL 3522090, at \*23-24 (E.D. Pa. Sept. 3, 2010) (S&P analyst downgrade did not "qualify as a corrective disclosure" because "no reasonable jury could find that these disclosures revealed to the market new information about the falsity of Defendant's alleged misstatements"); In re BankAtlantic Bancorp, Inc. Sec. Litig., 07-cv-61542, 2010 WL 6397500, at \*28 (S.D. Fla. Aug. 18, 2010) (analyst downgrade did not show loss causation under either a "corrective disclosure" or "materialization of concealed risk" analysis).



## E. The Events Of March 30, 2008 Do Not Show Loss Causation

Finally, Plaintiffs seek damages for Schering's stock price decline on March 31, 2008, the day after the ENHANCE study was published in the *New England Journal of Medicine* ("NEJM") and discussed at the ACC conference. Plaintiffs argue this was the first time that data quality, exploratory subgroup and secondary endpoint statistics were reported. (Pl. Br. 17-19.)

This argument must fail because it confuses disclosure of the details of the ENHANCE trial with disclosure of the alleged fraud. Even if new statistical information was reported on March 30, 2008, Plaintiffs have not presented evidence that Defendants knew those details on January 14, 2008.<sup>6</sup> Instead, Plaintiffs claim that Defendants knew it was "highly improbable" that Vytorin would reduce IMT more than Zocor alone in the ENHANCE trial. (Gordon Aff., Ex. 24 at 27-29, 75.) And that was disclosed on January 14. (Gordon Aff., Ex. 1 ¶¶ 172, 364; Ex. 30 ¶ 60.)

Plaintiffs also claim that March 30, 2008 was the first time physicians could appreciate the clinical significance, and investors could appreciate the commercial significance, of the ENHANCE trial. (Pl. Br. 22-26.) But once Defendants disclosed the very facts they allegedly knew and withheld, additional negative information about the trial was within the portfolio of risks assumed by shareholders. As a matter of law, only an economic loss caused by disclosure of the alleged fraud can show loss causation. See Dura Pharm., Inc. v. Broudo, 544

Indeed, Plaintiffs concede that the information released on March 30, 2008 was "not yet complete or peer reviewed" as of January 2008, (Pl. Br. 13) and that "a full assessment of the study results [was] not even possible" in January 2008 because Dr. Kastelein had not completed the analyses. (Pl. Br. 25; Gordon Aff., Ex. 36.) They also emphasize that "between the January and March Disclosures, the patients' baseline IMT and LDL values *changed*," and that Dr. Kastelein stated when he published the data quality statistics in March 2008 that they were "three times as good" as he had previously assumed. (Pl. Br. 22, 24.)

Plaintiffs' purported evidence that Defendants foresaw the economic consequences that actually materialized after March 30, 2008 is no more convincing. Plaintiffs claim that, according to a 2006 internal forecast of the Merck/Schering-Plough joint venture,

U.S. 336, 346 (2005) (to show loss causation, "fraudulent conduct [must] proximately cause[] the plaintiff's economic loss"); Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 173 (3d Cir. 2001) (plaintiff must prove that the "fraudulent misrepresentation actually caused the loss suffered"); Semerenko v. Cendant Corp., 223 F.3d 165, 184, 184-86 (3d Cir. 2000) (stock price must have "dropped in response to disclosure of the alleged misrepresentations").

That Schering's stock price declined on March 31 also does not show that the loss was caused by the alleged fraud. (Pl. Br. 21 n.19.) Economic loss, or damages, is a separate element from loss causation. *See Dura*, 544 U.S. at 341-42; 15 U.S.C. § 78u-4(b)(4). The question on this motion is whether the economic loss on March 31 was *caused* by the alleged fraud. *See D.E.&J. Ltd. Partnership* v. *Conaway*, 133 F. App'x 994, 1000-01 (6th Cir. 2005) ("the observation that a stock price dropped on a particular day . . . is not the same as an allegation that a defendant's fraud caused the loss"); *In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 554 (S.D.N.Y. 2008), *aff'd*, 597 F.3d 501 (2d Cir. 2010) (citing *In re Merck & Co., Inc., Sec. Litig.*, 432 F.3d 261, 270 (3d Cir. 2005)) ("It is clear that a

(Reply Memorandum of Law in Support of Merck Defendants' Motion for Summary Judgment, at 4-7, *In re Merck & Co., Inc. Vytorin/Zetia Sec. Litig.*, 08-cv-2177 (D.N.J. filed May 18, 2012.))

characterization of previously disclosed facts can cause a loss, just not one attributable to the alleged fraud.").

#### III.

## DEFENDANTS DID NOT UNDERMINE THEIR JANUARY 14, 2008 DISCLOSURE

In their opposition brief, Plaintiffs raise three new statements which, they claim, undermined the January 14 disclosure. Those statements, however, did not suggest that the ENHANCE trial had not failed:

- Plaintiffs quote Schering's former CEO, Fred Hassan, as saying after January 14, 2008 that it was too early to make "too many judgments," that it was "important that the scientific process be respected," and that Schering looked forward to the ACC meeting where the results could be "discussed by the scientific community." (Pl. Br. 27.) But this does not support the claim that Defendants' made false excuses for the ENHANCE result. Certainly, Mr. Hassan did not suggest that Vytorin would outperform Zocor in reducing IMT.
- Plaintiffs quote Merck's then-General Counsel, Kenneth Frazier, as stating that

  (Pl. Br. 28 n.23.) Plaintiffs ignore that in the very pages of testimony they cite, Mr. Frazier made clear

  (Graziano Decl., Ex. 195 at 113-118.)

  (id. at 116), this does not mean that the ENHANCE trial had not failed or that the factual information Defendants allegedly possessed had not been disclosed.
- Finally, Plaintiffs quote Merck CFO, Peter Kellogg, as stating on March 17, 2008: people who go to ACC would "learn important new information on ENHANCE" because "the full data set with all of the subset analysis and different perspectives that go with it would be

important." (Pl. Br. 28.) This also does not show that Defendants "blamed" the negative ENHANCE result on a false explanation, or somehow suggested that ENHANCE would be a victory for Vytorin.

Finally, Schering did not make any untrue statement about the ENHANCE patient population – much less one that was "corrected" on March 30, 2008. On March 30, 2008, Dr. Kastelein himself proposed that one explanation for the negative result was that the ENHANCE trial enrolled only patients who were genetically predisposed to high levels of LDL cholesterol, and whose prior treatment with high-dose statins may have made them resistant to further changes in IMT. (Gordon Aff., Ex. 10, at 1440-42; Ex. 12 at –35-36.) Similarly, in 2009 – following an extensive review of the ENHANCE study – the FDA proffered the same possible explanation for the trial result, stating that the patients had "received prior lipid-altering or statin therapy and had relatively normal cIMT values at baseline." (Gordon Aff., Ex. 4.) Thus, the reason why the ENHANCE trial failed remained an open issue on and after March 30, 2008. That the trial had failed – the information Defendants allegedly possessed – was undeniably disclosed on January 14, 2008.

## **Conclusion**

For the foregoing reasons, Defendants' motion for partial summary

judgment should be granted.

Dated: May 18, 2012

Respectfully submitted,

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